Message Text

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PAGE 01 STATE 256467

62
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 /024 R

66618
DRAFTED BY DHEW/FDA:JRWEINROTH:AMS
APPROVED BY OES/APT/BMP:MBEAUBIEN
DHEW/OIH:MACODDING
EUR/CE:BAFLATIN (INFO)
EUR/CE:DANDERSON (INFO)
---------- 054841
R 292131Z OCT 75
FM SECSTATE WASHDC
TO AMEMBASSY VIENNA
AMEMBASSY BONN

UNCLAS STATE 256467

E.O. 11652: NA

TAGS: OGEN ETRD TBIO AU GW

SUBJECT: FDA ADVISORY - INADEQUATE HEPATITIS B SURFACE ANTIGEN (HBSAG) TESTING

1. FDA ADVISES THAT THE FOLLOWING ITEM IS BEING RECALLED FROM THE MARKET:

PRODUCT: FROZEN SOURCE PLASMA (HUMAN) LABELLED IN PART: "XXX SOURCE PLASMA (HUMAN)XBLEED NO.XDONOR NO.XXNON-REACTIVE FOR HEPATITIS B ANTIGEN BY RIA METHOD. XSTORE AT -20 DEGREES CENTIGRADE OR COLDERX CAUTION: FOR MANUFACTURING USE ONLY, DO NOT USE IF EVIDENCE OF THAW-ING. XORLANDO PLASMA CORPORATION, 132 SOUTH MAGNOLIA AVENUE, ORLANDO,

FLORIDA 32801XU.S. LICENSE NO.XXX". U.S. LICENSE NUMBER ON UNITS IS 538.

LOT NUMBERS: ALL LOTS OF SOURCE PLASMA (HUMAN) MANUFACTURED SINCE 7/1/74 ARE UNDER RECALL.

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PAGE 02 STATE 256467

MANUFACTURER:

ORLANDO PLASMA CORPORATION
132 S. MAGNOLIA AVENUE
ORLANDO, FLORIDA 32801

RECALLING FIRM:
AUTOMATED MEDICAL LABORATORIES,HINC.
7501 N.W. 66TH ST.
MIAMI, FLORIDA 33166

THE RECALLING FIRM IS THE PARENT CORPORATION FOR ORLANDO PLASMA CORP.

REASON FOR RECALL:
THE RECALL IS BASED UPON FINDINGS OF FDA INSPECTIONS WHICH DISCLOSED INADEQUATE HEPATITIS B SURFACE ANTIGEN TESTING PROCEDURES/CONTROLS, POOR RECORD KEEPING, SHIPMENT OF HBSAG REACTIVE UNITS, ETC.

2. FOREIGN CONSIGNEES AS FOLLOWS:

A. IMMUNO, A.G.
INDUSTRIESTRASSE 72, A-1220
VIENNA, AUSTRIA DATE OF SHIPMENT JANUARY 1975 469.545 LITERS

B. HAEMO-MED. A.G.
6000 FRANKFURT AM-MAIN 1
RODENBERGWEG, WEST GERMANY

FEBRUARY 1975 - 924.405 LITERS
MARCH 3, 1975 - 2,492.680 LITERS
OARCH 31, 1975 - 1,690.940 LITERS
MAY 25, 1875 - 2,002.880 LITERS

3. POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES HAVE RECEIVED RECALL LETTER FROM FIRM AUTOMATED MEDICAL LABORATORIES, INC. SENT 10/16/75. IN ADDITION HAEMO-MED HAS BEEN IDENTIFIED AS A BROKER; THEREFORE, FDA DESIRES THAT SPECIFIC INFORMATION BE OBTAINED IDENTIFYING THE SECONDARY CONSIGNEES TO WHICH THE PLASMA WAS REDISTRIBUTED FOR FURTHER MANUFACTURING. KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: PUBLIC HEALTH, COMMUNICABLE DISEASES, HEPATITIS
Control Number: n/a
Copy: SINGLE
Draft Date: 29 OCT 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: JRWEINROTH:AMS
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Executive Order: N/A
Errors: N/A
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TAGS: OGEN, ETRD, TBIO, AU, GE
To: VIENNA BONN
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006